Remarks

Upon entry of the foregoing amendments, claims 1 to 6, 8 to 20, 36, 38, 40, 42, 44, 46 and 48 to 64 will be pending in this patent application. Claims 8 to 14, 36, 38, 40, 42, 44, 46, 50, 51, 58 and 60 to 63 have been amended, without prejudice.

Claims 7, 21 to 35, 37, 39, 41, 43, 45, and 47 have been canceled without prejudice as being directed to non-elected subject matter. Applicants reserve the right to present the subject matter of claims 7, 21 to 35, 37, 39, 41, 43, 45, and 47 in a later-filed divisional patent application.

The Office Action includes rejections under 35 U.S.C. § 112, first paragraph, and 35 U.S.C. § 103(a). In view of the remarks to follow, Applicants request that these rejections be reconsidered and withdrawn.

Discussion of the Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 9 to 20, 36, 38, 40, 42, 44, 46, 48 and 50 to 64 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking support in the specification (Action at 3). In this regard, the Action contends that the specification does not teach the link between the modulation of the NHE-1 receptor and the ***prevention*** of any condition or disease (id.). Although Applicants respectfully disagree, claims 8 to 14, 36, 40, 42, 44, 46, 50, 51, 58 and 60 to 63 have been amended to delete the term "prophylaxis" in order to advance prosecution of this patent application. Accordingly, reconsideration and withdrawal of the rejection are requested respectfully.[1]

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[1] The Action alleges that Applicants, in their Reply to the Action dated June 29, 2005, argued that "there is no requirement for the specification to have written description: (Action at 3). Indeed, Applicants made no such argument; Applicants clearly argued that the June 29, 2005 Action had misapplied the law with respect to the written description requirement of 35 U.S.C. §

Discussion of the Rejection Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 9 to 20, 36, 38, 40, 42, 44, 46, and 48 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement with regard to the broad use of the compounds of claim 1 for the treatment of any disease linked to the NHE-1 receptor. Applicants respectfully traverse this rejection.

The Action asserts that the "specification fails to provide sufficient support of the broad use of the compounds of claim 1 for the treatment of ***any*** disease [linked to an NHE recptor]" (Action at 7) (emphasis added). The instant method claims, however, recite specific diseases and conditions and, thus, are not directed to the treatment of ***any*** disease linked to a NHE receptor. The prior art publications of record demonstrate the art-established link between such diseases and conditions and the inhibition of NHE receptors. Despite this evidence, the Action contends that "one of ordinary skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compounds of the instant claims, with no assurance of success" (Action at 8). Applicants' claims, however, do not require a specific degree of success and the Action has not provided any evidence or technical reasoning to demonstrate that the compounds having the lower activities would ***not*** result in ***some degree*** of treatment. Moreover, even if such differences in activities were to require those of ordinary skill in the art to engage in ***some*** experimentation (*arguendo*), the Action has not provided any evidence or technical reasoning to show that such experimentation would be ***undo***. Thus, in view of the evidence previously submitted by Applicants, the Action has failed to demonstrate that Applicants' working examples, for example, are insufficient to enable the claimed invention.

The Action also takes the position that the identification of the diseases or conditions

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112, first paragraph. Applicants maintain their position that the Office continues to misapply the law to the present application.

treatable by the presently claimed compounds would constitute undue experimentation (Action at 8). This assertion, however, is confusing because Applicants' claims already identify specific conditions to be treated with the compounds of the claimed invention. Again, the Action appears to have overlooked the plethora of literature that Applicants previously submitted that shows the predictable relationship between the inhibition of NHE1 and the diseases recited in Applicants' claims. In this regard, Exhibit A of Applicants' Reply to the Action dated June 29, 2005 presented a summary of the literature of which Applicants are aware (along with copies of the literature), thus providing strong evidence that those of ordinary skill in the art know the link between inhibition of NHE and the conditions recited in Applicants' claims and that such conditions can be treated or prevented by inhibition of NHE. Indeed, the MPEP makes it clear that "[a] patent need not teach, and preferably omits, what is well known in the art." MPEP § 2164.01. The Action, however, has not yet responded to this evidence by providing evidence or technical reasoning to support its position that the identification of the diseases or conditions treatable by the presently claimed compounds would constitute undue experimentation.

Despite the guidance provided by the 16 compounds exemplified in Applicants' specification, the Action further asserts that identification of the specific compounds encompassed by the present claims that can treat or prevent a specific disease or condition would constitute undue experimentation (Action at 8). Significantly, however, there is no legal requirement that Applicants exemplify every compound that falls within the scope of the claims. Rather, all that is required is that one skilled in the art be able to practice the claimed invention, in view of the level of knowledge and skill in the art, without undue experimentation. In this regard, the Office Action has provided no factual evidence or technical reasoning to support the bare assertions contained therein. Accordingly, reconsideration and withdrawal of the rejection are requested respectfully.

Discussion of the Rejection Under 35 U.S.C. § 103(a)

Claims 1 to 6, 8 to 20, 36, 38, 40, 42, 44, 46, and 48 to 64 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over European Patent No. 0708091 to Kitano et al. ("Kitano"). Applicants respectfully traverse this rejection as one of ordinary skill in the art presented with Kitano at the time of the present invention would not have been motivated to modify its teachings in such a way as to produce Applicants' claimed invention.

The present claims recite that substituent "Ar" comprises a 9 to 10 member bicyclic heteroaryl ring having one to three nitrogen atoms. The Action admits that at least one difference between Kitano and the present claims is that Kitano does not disclose the Ar substituent as a 9 to 10 member heterocyclic ring (Action at 10). Kitano, however, is incapable of providing the requisite art-suggested motivation to modify its teachings in such a way as to include a 9 to 10 member heterocyclic ring at the Ar position because Kitano –throughout the document – limits the equivalent Ar substituent to ***5 to 6 member*** heteroaryl rings when such rings contain only nitrogen as the heteroatom.

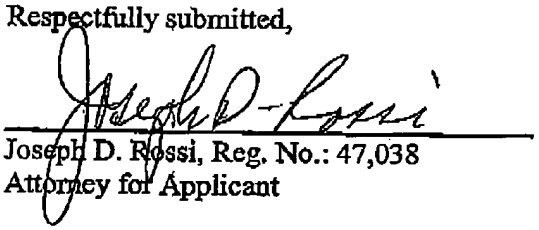
The Action contends, however, that the motivation to modify Kitano is provided through use of the exemplified Ar substituents pyridine and piperidine (*id.*). But pyridine and piperidine (which is not even an aryl group) are 6-membered rings, which clearly fall within Kitano's definition of Ar. Moreover, Applicants could not even find Kitano's recitation of piperidine. Therefore, Kitano's disclosure of pyridine (and alleged disclosure of piperidine) ***does not*** provide any modification to modify the definition of Ar in Kitano to include a 9 to 10 member heterocyclic ring as is recited in Applicants' claimed invention. Accordingly, reconsideration and withdrawal of the rejection over Kitano are requested respectfully.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Action of record. Applicants respectfully submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are requested respectfully.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. 18-1982 in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,



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